

WHAT IS CLAIMED IS:

1. A method for sterilizing and/or deactivating adventitious agent(s)
and/or within biological material which comprises
 - b) packaging the biological material;
 - 5 c) altering the atmosphere of the packaged biological material to
reduce the level of oxygen in contact with the packaged biological material; and,
c) irradiating the packaged biological material while the
atmosphere of the packaged biological material is in the altered state to sterilize
and/or deactivate adventitious agents.
- 10 2. The method of Claim 1 wherein the adventitious agent is at least one
member selected from the group consisting of bacterial, mold, yeast, fungus, virus and
prions.
3. The method of Claim 2 wherein the virus is an enveloped or non-
enveloped virus.
- 15 4. The method of Claim 2 wherein the virus is selected from the group
consisting of HIV, Hepatitis A, Hepatitis B, Hepatitis C, polio, herpes, parvo, west
nile, and SARS.
5. The method of Claim 1 wherein the biological material is selected
from the group consisting of food, tissue, therapeutically useful substance and
20 therapeutically useful device.
6. The method of Claim 1 wherein the tissue is bone.
7. The method of Claim 1 wherein the tissue is donor bone.
8. The method of Claim 7 resulting in the conservation of the
biomechanical strength of the bone.

9. The method of Claim 7 resulting in the conservation of the osteoconductivity, growth factor activity, signal transduction and/or transcription factor activity of the bone.
10. The method of Claim 1 resulting in the conservation of the *in vitro* degradation characteristics of the bone.
11. The method of Claim 1 wherein the biological material is subjected to at least one pre-packaging procedure, said procedure being one of:
- (i) applying an antioxidant to the biological material,
 - (ii) removing lipid from the biological material,
 - 10 (iii) removing metal ions from the biological material,
 - (iv) removing water from the biological material, and
 - (v) reducing the bioburden of the biological material.
12. The method of Claim 11 wherein the antioxidant is at least one member selected from the group consisting of ascorbic acid, beta carotene, selenium, 15 coenzyme Q10, tocopherols, retinoids and carotenoids.
13. The method of Claim 11 wherein lipid is removed from the biological material by a lipid-removing procedure which includes contacting the biological material with at least one lipid-dissolving solvent and/or at least one lipase.
14. The method of Claim 11 wherein metal ions are removed from the 20 biological material by contacting the biological material with at least one chelating agent for metal ions.
15. The method of Claim 14 wherein the chelating agent is at least one member selected from the group consisting of aminopolycarboxylic acids, aminopolycarboxylic salts, diethylenetriaminepentaacetic acid, nitrilotriacetate, 25 diethylenetriaminepentaacetic acid, ethylene diamine, N,N-

bis(carboxymethyl)glycine, gluconates, organophosphonates, sodium silicate, magnesium sulfate, ferulic acid, sodium hydrosulfite, hydrogen peroxide, gluconic acid, anthraquinone, citric acid and dimercaprol.

16. The method of Claim 11 wherein water is removed from the biological
5 material by at least one of vacuum drying, lyophilization and displacement of water with at least one other liquid.

17. The method of Claim 11 wherein the reduction of the bioburden of the biological material is accomplished by at least one of exposing the biological material to ionizing radiation and/or ultraviolet radiation, pasteurization, contact with at least
10 one antibiotic, antiviral and/or antimycotic agent.

18. The method of Claim 17 wherein the biological material is exposed to a total ionizing radiation dose of from about 2 to about 50 kGy.

19. The method of Claim 17 wherein the biological material is exposed to a total ionizing radiation dose of from about 5 to about 25 kGy.

15 20. The method of Claim 17 wherein the biological material is exposed to ultraviolet radiation at a wavelength of from about 1 nm to about 400 nm for about 1 minute to about 1 hour.

21. The method of Claim 17 wherein the biological material is exposed to ultraviolet radiation of from about 5 nm to about 250 nm for from about 5 to about 30
20 minutes.

22. The method of Claim 17 wherein pasteurization of the biological material is carried out from about 60 to about 120 ° C for from about 1 minute to about one hour.

23. The method of Claim 17 wherein pasteurization of the biological

material is carried out from about 90 to about 110 ° C for from about 1 minute to about one hour.

24. The method of Claim 1 wherein in packaging step (a), the biological material is placed within a gas-permeable or gas-impermeable package.

5 25. The method of Claim 1 wherein in packaging step (a), the biological material is placed within a microbe-impermeable package.

26. The method of Claim 1 wherein in packaging step (a), the biological material is placed within an inner package and the inner package is thereafter placed within an outer gas-impermeable package.

10 27. The method of Claim 1 wherein in packaging step (a), the biological material is placed within an inner package and the inner package is thereafter placed within an outer microbe-impermeable package.

28. The method of Claim 26 wherein the outer package is a bulk package.

29. The method of Claim 27 wherein the outer package is a bulk package.

15 30. The method of Claim 1 wherein altering the atmosphere of the packaged biological material is carried out by at least one of replacing the original atmosphere with an inert atmosphere, a reducing atmosphere or a mixture of inert atmosphere and reducing atmosphere, and removing original atmosphere under vacuum.

20 31. The method of Claim 1 wherein prior to irradiating step (c), the packaged biological material is cooled or heated and while in the cooled or heated state is subjected to irradiating step (c).

32. The method of Claim 30 wherein the inert atmosphere comprises at least one inert gas selected from the group consisting of nitrogen and argon.

33. The method of Claim 30 wherein the reducing atmosphere comprises at least one reducing gas selected from the group consisting of hydrogen and carbon monoxide.
34. The method of Claim 30 wherein the mixture of inert atmosphere and reducing atmosphere contains from about 0.5 to about 99% by volume reducing gas.
35. The method of Claim 30 wherein original atmosphere is removed under a vacuum of from about 1 to about 200 torr.
36. The method of Claim 31 wherein the biological material is subjected to cooling to a temperature of from just below ambient to about -200 ° C.
37. The method of Claim 36 wherein the biological material is subjected to cooling to a temperature of from about 0 to about -75 ° C.
38. The method of Claim 31 wherein the biological material is subjected to heating to a temperature of from just above ambient to about 100 ° C.
39. The method of Claim 38 wherein the biological material is subjected to heating to a temperature of from about 30 to about 80 ° C.
40. The method of Claim 1 wherein in irradiating step (c), the total dose of irradiation is from about 2 to about 50 kGy.
41. The method of Claim 1 wherein in irradiating step (c), the total dose of irradiation is from about 5 to about 25 kGy.
42. The method of Claim 1 wherein irradiating step (c) is carried out by multiple radiation dosing.
43. The method of Claim 42 wherein irradiating step (c) is carried out in a two-dose or three-dose sequence.
44. The method of Claim 11 wherein the biological material is bone.
45. The method of Claim 13 wherein the biological material is bone.

46. The method of Claim 14 wherein the biological material is bone.
47. The method of Claim 17 wherein the biological material is bone.
48. The method of Claim 24 wherein the biological material is bone.
49. The method of Claim 25 wherein the biological material is bone.
50. The method of Claim 26 wherein the biological material is bone.
51. The method of Claim 27 wherein the biological material is bone.
52. The method of Claim 30 wherein the biological material is bone.
53. The method of Claim 31 wherein the biological material is bone.

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